



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,487	03/26/2001	Susanne Dagmar Pippig	4-31193A	9170
1095	7590	01/30/2004	EXAMINER	
THOMAS HOXIE			LI, RUIXIANG	
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY			ART UNIT	
ONE HEALTH PLAZA 430/2			PAPER NUMBER	
EAST HANOVER, NJ 07936-1080			1646	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,487

Applicant(s)

PIPPIG ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 12, 14, 17-20 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 11, 12, 14, and 17-20 is/are rejected.
- 7) ☒ Claim(s) 5 and 25-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims and Status of Application

The amendment filed on November 6, 2003 has been entered. No claims have been amended. Claims 1-9, 11, 12, 14, 17-20, and 25-28 are pending and are under consideration. Claims 1-4, 6-9, 11, 12, 14, and 17-20 are rejected, whereas claims 5 and 25-28 are objected.

Oath/Declaration

The objection to oath or declaration appeared in the Office Action Summary sheet is an error. The objection to the supplemental declaration submitted on March 31, 2003, as set forth in Paper No. 18 (6/3/2003), has been withdrawn, as indicated in Paper No. 20 (7/15/2003).

Claim Rejections Under 35 U. S. C. § 103 (a)

The rejection of claims 1-4, 6-9, 11, 12, 14, and 17-20 under 35 U.S.C. 103(a) as being unpatentable over Bordignon et al. (WO 95/06723) in view of Valenzuela et al. (WO 97/21811), as set forth in previous office action (Paper No. 20, July 15, 2003), remains.

Beginning at the middle of page 6 of Applicant's response, Applicants, citing case law, summarize the legal requirements for the obviousness rejection. The Examiner does not

Art Unit: 1646

dispute over these requirements; rather, the difference appears to how to interpret these requirements for obviousness.

Beginning at the bottom of page 7, Applicants argue that the Examiner has failed to provide an expressed or implied motivation to combine the cited references. Applicants submit that merely summarizing the teachings of the two references does not constitute a showing of motivation to combine them.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. It is the benefit of the method of marking a mammalian cell taught by Bordignon et al. and the unique property of MuSK-R taught by Valenzuela et al. that motivates one skilled in the art to combine the teachings of Bordignon et al. and Valenzuela et al. Specifically, expression of a cell surface MuSK-R or a mutated MuSK-R receptor in human hematopoietic cells would not be expected to effect any signal transduction, interfere with the function of the cells, and thus is effective and usable in gene therapy, since a MuSK-R is not naturally expressed in human hematopoietic cells. Therefore, an artisan would be motivated to make an mMuSK-R in view of the teachings of Bordignon et al. and Valenzuela et al. and use such a mutant as a masking marker for the genetically modified cells.

Beginning at page 9, Applicants argue that the obvious rejection has been based on impermissible hindsight. Applicants argue that the Examiner did not make clear any specific understanding or principle within the knowledge of a skilled artisan that would

Art Unit: 1646

motivated or suggest to one with no knowledge of Applicants' claimed invention to make the combination. Applicants further submit that the Examiner's use of hindsight is clearly evidenced by the fact that the references cited by the Examiner are essentially the same references cited by the Applicants in the specification.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the motivation for an artisan to combine the teachings of Bordignon et al. with Valenzuela et al. clearly exists in the art; that is, expression of a cell surface MuSK-R or a mutated MuSK-R receptor in human hematopoietic cells would not expected to effect any signal transduction, interfere with the function of the cells, and thus is effective and usable in gene therapy, since a MuSK-R is not naturally expressed in human hematopoietic cells, as set forth above and in the previous office action.

The Examiner notes that Applicants' argument that the rejection has been based upon impermissible hindsight has no ground. According to Applicants' argument, if a reference is cited in specification, any obviousness rejection using such a reference will be considered as hindsight reconstruction. If Applicants' argument held, there would be no obviousness rejection in the case where potential art is cited in the application. Obviously, this is incorrect. 35 U. S. C. § 103 (a) does not prohibit an Examiner from using a reference for writing a rejection simply because the reference is cited in the application by Applicants. In the instant case, an artisan would readily find the references of Bordignon et al. and Valenzuela et al. by simple searching the literature from a database, e.g., Medline. Most importantly, all the benefits of methods taught by

Art Unit: 1646

Bordignon et al. and the unique properties of cell surface MuSK-R or its mutants, which motivate an artisan to combine them, exist in the two references. Therefore, the rejection has been based upon the teachings of the cited references, not impermissible hindsight.

At page 10, Applicants conclude the argument and urge that the rejection under 35 U.S.C. § 103 (a) be withdrawn. The Examiner believes that the *prima facie* obviousness has been established for the reasons set forth above and in the office action of record.

Claim Objections

The objection of claims 5 and 25-28 as being dependent upon a rejected base claim, as set forth at page 6 of Paper No. 20 remains. Applicants have not amended the claims as requested.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1646

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Application/Control Number: 09/817,487
Art Unit: 1646

Page 7

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
January 15, 2004

Gary d. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600